K080305

APR - 7 2008

XI. 510(k) SUMMARY (Nexcomp)

Submitter: Tae-Hoon Kim, Manager QM, Meta Biomed Co., Ltd, Cheongwongun Chungbuk, Korea. Tel: 82-43-218-1983.

Classification Name and Number: Tooth Shade Resin Material, Class II, EBF.

Common/Usual Name: Composites, restoratives.

I. **Proprietary Name:** Nexcomp

II. **Registration No.:** 9681254

III. **Compliance with Performance Standards:** Nexcomp complies with ISO 4049:2000(E), Polymer-based filling, restorative, and luting materials. Also, followed "Guidance for Industry and FDA Staff; Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions"

IV. **Description of the Device:** Nexcomp is a highly filled (75 wt.%), light-cured hybrid composite. The material is radiopaque and indicated for all types of cavity preparations. The hybrid blend has an ultra fine filler and 40 nm silica particles. Nexcomp will be marketed in *incisal, body translucent, and body opaque* shades which correspond with the Vita shade guide.

Nexcomp bonds micromechanically and chemically to prepared tooth surfaces, dental primers and bonding resin adhesives through copolymerization of its air-inhibited layer. It's color can be matched with various shades of standard color guides. It is available in tubes which are designed to be fitted into a screw-syringe with a body cap seal.

V. **Labels and Labeling:** Draft labels of Nexcomp and instructions for use are provided, together with warnings and contra-indications.

VI. **Substantial Equivalence:** These devices are equivalent to devices manufactured and sold before 1976, having a U. S. classification number (code) EBF, and those described under 21 CFR 872.3690. Each is also equivalent to several devices currently on the market that have been cleared by the premarket notification—510(k) process. Some of these are outlined below:

1. K070583, Nano Composite, Cosmedent, Inc.,

2. K052097, Ceram X Universal Mano-Ceramic Restorative, Dentsply, Inc.
3. K003361, Renew LS-2, Bisco, Inc.,
4. K982729, Renew, Bisco, Inc.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

K080305

APR - 7 2008

XI. **510(k) SUMMARY (Meta Etchant)**

Submitter: Tae-Hoon Kim, Manager QM, Meta Biomed Co., Ltd, Cheongwongun Chungbuk, Korea. Tel: 82-43-218-1983.

Classification Name and Number: Tooth Shade Resin Material, Class II, EBF.

Common/Usual Name: Etching gel.

I. **Proprietary Name:** Meta Etchant.

II. **Registration No.:** 9681254

III. **Compliance with Performance Standards:** There appear to be no applicable standards for etching gels, however, we followed "Guidance for Industry and FDA Staff; Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions".

IV. **Description of the Device:** Meta Etchant is a thickened, colored, phosphoric acid semi-gel designed to prepare tooth surfaces (dentin and enamel) for application of a bonding agent, cementation, or restorative materials.

V. **Labels and Labeling:** Draft labels of Meta Etchant and instructions for use are provided, together with warnings and contra-indications.

VI. **Substantial Equivalence:** These devices are equivalent to devices manufactured and sold before 1976, having a U. S. classification number (code) EBF, and those described under 21 CFR 872.3690. Each is also equivalent to several devices currently on the market that have been cleared by the premarket notification—510(k) process. For Meta Etchant, some predicates are:

1. K062409, K-Etchant Gel, Kuraray Medical Inc.,
2. K022492, Pulpdent Semi-Gel Etch, Pulpdent Corporation,

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tae-Hoon Kim
QM Manager
Meta Biomed Company, Limited
441-12 Mo Choong Dong
Cheong Ju Cheong City, Chung Buk
REPUBLIC OF KOREA

APR - 7 2008

Re: K080305
Trade/Device Name: Nexcomp and Meta Etchant
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin
Regulatory Class: II
Product Code: EBF, KLE
Dated: January 19, 2008
Received: January 5, 2008

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

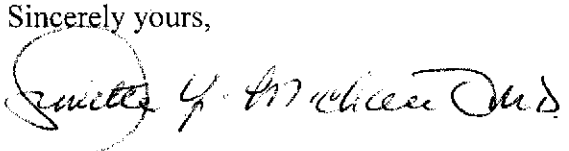
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X.1 Indications for Use: [Separate Page]

510(k) Number: ~~NA~~ K080305

Device Name: Meta Etchant

Indications for use:

Meta Etchant is intended for use in dentin/enamel etching to prepare the tooth surface for application of a bonding agent.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080305

X. Indications for Use: [Separate Page]

510(k) Number: ~~NA~~ K080305

Device Name: Nexcomp

Indications for use:

Nexcomp is intended to restore carious lesions or structural defects in teeth.
It is indicated for Class I, II, III, IV, and V restorations, core-buildup to replace missing tooth structure, for splinting and for diastema closure, direct veneers, composite and porcelain repairs.

Prescription Use___X___ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K080305